



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SB

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/379,424	08/23/99	BOLMSJO	M 4298-137

DIANE DUNN MCKAY
MATHEWS COLLINS SHEPHERD & GOULD P A
100 THANET CIRCLE SUITE 306
PRINCETON NJ 08540

QM12/1027

EXAMINER

GIBSON, R

ART UNIT

PAPER NUMBER

3739

DATE MAILED:

4
10/27/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/379,424

Applicant(s)

Bolmsjo

Examiner

Roy Gibson

Group Art Unit

3739



☒ Responsive to communication(s) filed on Dec 13, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-16 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-3, 5-9, and 12-15 is/are rejected.

☒ Claim(s) 4, 10, 11, and 16 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 3739

DETAILED ACTION

Claim Objections

Claims 1 and 12 are objected to because they include reference characters which are not enclosed within parentheses.

Reference characters corresponding to elements recited in the detailed description of the drawings and used in conjunction with the recitation of the same element or group of elements in the claims should be enclosed within parentheses so as to avoid confusion with other numbers or characters which may appear in the claims. See MPEP § 608.01(m).

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8, 9 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Behl (5,222,938).

As to claim 1, Behl discloses a device for heat treatment of a hollow body organ, such as a prostate [see col. 4, lines 58-65, and the examiner maintains that “and the like” can refer to the prostate as verified by Kalb et al. (5,007,897) in the abstract, lines 1-6], comprising a treatment

Art Unit: 3739

catheter (Figure 11, # 100) with an expandable fluid reservoir and first heating means (coils 102, 104 and 106) which emits electromagnetic radiation (infrared when heated with conventional A.C. current or microwave if alternatively heated from a MW generator (see col. 7, lines 20-22 and col. 11, line 45-col. 12, line 28) for heating of the surrounding tissue, the treatment catheter being provided with a free end which is insertable through the urethra into the urinary bladder of a patient and a second end connected to an energy supply unit arranged outside of the patient's body, wherein second heating means (110) is provided in thermal contact with the liquid of the fluid reservoir (Figure 11, # 112) for heating of the liquid, the fluid reservoir positioned external to the treatment catheter, and the first and second heating means are operatively connected with the energy supply unit (see also col. 8, lines 46-59 and col. 9, lines 6-18).

As to claims 8 and 9, Behl discloses that the energy supply unit is connected to the first heating means and to the second heating means via an electronic unit (controller), and wherein the electronic unit is provided for simultaneous supply (claim 8 limitation) of energy to the two heating means (col. 7, lines 28-37 and col. 11, line 62-col. 12, line 17) and alternatively, non-simultaneous supply (claim 9 limitation) of energy to the two heating means (col. 12, lines 18-28 and a separate heating element inherently can be energized at any time in relation to the other).

As to claim 12, Behl discloses a method for heat treatment of a hollow body organ, such as a prostate [as detailed above and as verified by Kalb et al. (5,007,897) in the abstract, lines 1-6], comprising a treatment catheter (Figure 11, # 100) equipped with an expandable fluid reservoir and first heating means (coils 102, 104 and 106) which emits electromagnetic radiation

Art Unit: 3739

(infrared when heated with conventional A.C. current or microwave if alternatively heated from a MW generator for heating of the surrounding tissue) the treatment catheter being provided with a free end which is insertable through the urethra into the urinary bladder of a patient and a second end connected to an energy supply unit arranged outside of the patient's body, comprising the steps of:

operative connection of the first heating means to the energy supply unit,
positioning of the fluid reservoir externally to the treatment catheter so that it is in operative position it will expand and engage with the surrounding tissue (including an urethra which extends through the prostate adjacent to the prostate neck, which would be inherent if the organ is the prostate),

heating of liquid in the fluid reservoir through a second heating means (110) which is arranged to be in thermal contact with the liquid separately from the first heating means (col. 11, line 62-col. 12, line 17).

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3739

Claims 2, 3, 5-7 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Behl.

As to claims 2 and 5, Behl discloses that the second heating element (110) is an electrical lead resistance powered by a conventional A.C. (low frequency power supply), but lacks the specific disclosure that the first heating means (106, etc. of Figures 11 and 12) is a microwave antenna powered by a MW power supply. However, Behl does disclose that a MW antenna is an equivalent heating means of providing heat to the environment surrounding the catheter as required for the tissue to be treated (col. 7, lines 8-22). Therefore, at the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the device of Behl by replacing one or both of the heating means with a MW antenna and power supply, as an alternative equivalent means of heating the surrounding tissue of the hollow body organ. The motivation to replace the first heating means only with a MW antenna and generator is the well known efficiency of MW in heating the surrounding tissue directly, i.e., without having to heat a fluid first which then conducts the heat to the tissue.

As to claim 3, Behl further discloses that the second heating means (110) comprises a lead resistance (coil of wire) separated from the antenna element (as modified by the teaching presented in the rejection of claim 2 above) and provided axially displaced along the treatment catheter from the first heating means towards the free end of the catheter (Figure 11).

Art Unit: 3739

As to claim 6, Behl further discloses that the two and separate heating means with associated generators (as modified in the rejection of claim 2 above) can jointly supply energy (col. 12, lines 12-17).

As to claim 7, Behl discloses the general control system used to measure the temperature of the tissue to be treated by measuring the temperature of the fluid adjacent to the heating means (col. 7, lines 28-37). In addition, Behl discloses that in the configuration of Figures 11 & 12, that the heating means can be separate (col. 12, lines 25-28). Therefore, the examiner maintains that in this configuration it would have been obvious to provide a control system for each of the heating means and the surrounding tissue [or the surrounding fluid in the balloon (112)] by placing a temperature sensor as required along with separate feedback circuits for control of the heating supplies in order to control the temperature of the respective regions.

As to claim 13, Behl discloses simultaneous supply of energy to the two heating means as detailed in the rejection of claim 6 above.

As to claim 14, Behl discloses measuring of the tissue and fluid temperature as detailed in the rejection of claim 7 above.

As to claim 15, Behl discloses non-current supply of energy to the two heating means as detailed in the rejection of claim 9 above.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Behl in view of Rudie et al. (5,843,144). Behl discloses that a feed cable connects the energy supply unit to the

Art Unit: 3739

two heating means and that the heating means could optionally be microwave energy (col. 11, line 62-col. 12, line 17 and col. 7, lines 8-22). However, Behl lacks the specific disclosure of the structure of a MW coaxial cable which would be used in the optional case. But, Rudie et al. disclose a device for treating BRH with a microwave antenna and connecting coaxial cable in the catheter (col. 6, lines 58-65) and the examiner maintains that it is well known in the art of MW or coaxial cables that the inner conductor supplied the MW energy and the covering acts as a return lead.

Allowable Subject Matter

Claims 4, 10, 11 and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Eggers et al. ('282) disclose methods and apparatus for ablation of luminal tissues which also supports the assumption that the prostate treatment is the same as for a hollow body organ (col. 5, lines 4-9); Edwards ('968) discloses a uterine treatment device with an expandable member, first heating means and second related heating means (Figure 10), but the first heating

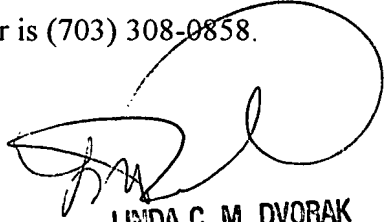
Art Unit: 3739

means is within the fluid reservoir; and van Hooydonk ('251) discloses a transcervical intrauterine applicator with two microwave heaters (Figure 11), but lacks a fluid reservoir.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Gibson whose telephone number is (703) 308-3520. The examiner can normally be reached on Monday-Friday from 9 am - 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Linda Dvorak, can be reached on (703) 308-0994. The fax phone number for this Group is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0858.



LINDA C. M. DVORAK
SUPERVISORY PATENT EXAMINER
GROUP 3700



RDG

October 26, 2000